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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,778	03/19/2004	Richard A. Gross	14690.011USA	7749

25461 7590 12/15/2008
SMITH, GAMBRELL & RUSSELL
SUITE 3100, PROMENADE II
1230 PEACHTREE STREET, N.E.
ATLANTA, GA 30309-3592

EXAMINER	
GOON, SCARLETT Y	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claims 1-3, 5, 6, 28-30, 55 and 58-74 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 August 2008 has been entered.

This Office Action is in response to Applicants' Amendment and Remarks/Arguments, filed on 25 August 2008, in which claims 4, 7-27, 31-54, 56 and 57 were cancelled, claimed 1-3 and 55 were amended to change the scope and breadth of the claim, and claims 58-74 are newly added.

Applicants indicate that support for the amendment to claims 1-3 and 55 can be found in the Specification on p. 5, line 4 – p. 6, line 15, that new claim 58 has been formulated based on the original claims, that new dependent claims 59-67 provide additional features for the invention found in the various examples of the original Specification, and that new claims 69-74 are identical with several of the original claims, but with dependencies changed to recoup the subject matter of cancelled claims. Applicants explicitly indicate that no new matter has been added. Upon consideration of

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the amendments, the Examiner respectfully disagrees that no new matter has been added. See claim rejections under 35 USC § 112.

Claims 1-3, 5, 6, 28-30, 55 and 58-74 will be examined herein.

Priority

This application claims priority to U.S. provisional application no. 60/456208 filed on 20 March 2003.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Rejections Withdrawn

In view of the amendment to the claims in application no. 10/807,961, now U.S. Patent No. 7,262,178 B2, the provisional double-patenting rejection of claims 1-3, 5-8, 12, 28-30 and 55-57 is hereby withdrawn.

In view of the cancellation of claims 4, 7-27, 31-54, 56 and 57, all rejections made with respect to claims 4, 7-27, 31-54, 56 and 57 in the previous Office Action are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 6, 28-30, 55 and 58-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "method for preparing dispensable sophorolipids" followed by "to form a sophorolipid ester" in claims 1, 2, 3, 55 and 58 render the claims herein indefinite. It is unclear whether Applicants intend to prepare natural sophorolipids or sophorolipid esters since the preamble of the claim and the preparation step disclose different sophorolipid compounds.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 28-30, 55, 64, 64-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to amended claims herein has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the steps of preparation as instantly claimed. Claims 1-3 and 55 has been amended to include a step of "treating the natural mixture with lipase in the presence of an alkoxide to form a sophorolipid ester" or treating the lactonic fraction with lipase "in the presence of an alkoxide". However, the original specification does not support treatment of the natural mixture with lipase in the presence of an alkoxide. As indicated on p. 5, line 4 through p. 6, line 15 of the original Specification, treatment of the natural mixture with an alkoxide does not occur in the presence of a lipase, but rather under reflux conditions.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that the Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claims 1-3, 5, 6, 28-30, 55, 64 and 64-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The rejected invention is drawn to a method for preparing dispensable sophorolipids having spermicidal and/or antiviral properties comprising a step which involves treating the natural mixture with lipase in the presence of an alkoxide to form a sophorolipid ester.

Breadth of claims: The claims specifically encompass treatment of a natural mixture of lactonic sophorolipids and non-lactonic sophorolipids with lipase in the presence of an alkoxide to form a sophorolipid ester.

State of the prior art/Predictability or unpredictability of the art: The skilled artisan would view that it is highly unlikely that treatment of a sophorolipid mixture with lipase in the presence of an alkoxide would result in a sophorolipid ester. Gotor *et al.* (PTO-892, Ref. U) teach that in an enzymatic transesterification reaction involving lipases, the election of the acyl donor is essential. Furthermore, it is necessary to know

the reactivity of the starting materials well in order to choose the acylating agent (p. 2189, column 2, first full paragraph). In order to avoid the reversibility of these processes, several acylating agents can be used such as activated esters, enol esters, anhydrides, oxime esters, thioesters, or 1-ethyoxy vinyl ester (p. 2189, column 2, first full paragraph). This teaching is further confirmed by González-Sabín *et al.* (PTO-892, Ref. V), which teach that lipase-catalyzed acylation of amines is an example of an aminolysis process assisted by a weak base (p. 1264, column 1, last incomplete paragraph). Although González-Sabín *et al.* teach lipase-catalyzed acylation of amines, the authors further indicate that it is accepted that the pathway is analogous to the acylation of alcohols (p. 1264, column 2, first incomplete paragraph).

Thus, the teachings of the prior art indicate that it is unlikely that lipase-catalyzed acylation would occur in the presence of an alkoxide, which is a strong base.

Amount of guidance/Existence of working examples: More importantly, there are **no** working examples present which show a method that comprises the step of treating the natural mixture with lipase in the presence of an alkoxide to form a sophorolipid ester. As indicated on p. 5 of the instant specification, synthesis of ethyl 17-L[(2'-O-β-D glucopyranosyl- β-D-glucopyranosyl)-oxy]-cis-9-octadecenoate 6',6"-diacetate is accomplished by first refluxing 2 g of dry crude sophorolipid with sodium ethoxide in a methanol solution, and then after purification, the resultant compound is treated with vinyl acetate in the presence of Novozym 435 (a lipase) to yield the product. No lipase is used in the initial step of the reaction when sodium ethoxide is used as the reagent.

Similar to the teaching of Gotor *et al.*, described above, lipase is used with vinyl acetate, an activated ester, not an alkoxide, as instantly claimed.

Lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of making the claimed compounds as recited in the instant claims.

Genetech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, e.g., the amount of guidance provided, the predictability of the art and the lack of working examples, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-63 are rejected under 35 U.S.C. 102(b) as being anticipated by journal publication by Bisht *et al.* (of record).

Bisht *et al.* disclose chemo-enzymatic synthesis of well-defined sophorolipid analogues. Sophorolipids were synthesized by fermentation of the cells of Candida bombicola (formerly known as *Torulopsis bombicola* as evidenced by Carr *et al.*, PTO-892, Ref. W) on glucose/oleic acid mixtures, to give lactones and open chain forms of sophorolipids (p. 780, column 2, Figure 1; p. 781, column 2, subheading "Experimental Section," paragraph 1; p. 784, column 1, first paragraph). The synthesis of methyl and ethyl sophorolipid esters was conducted by reaction of the natural mixture with sodium methoxide or sodium ethoxide under reflux conditions (p. 784, column 2, Scheme 1; p. 784, column 2, subheading "Synthesis of Ester Sophorolipid Derivatives"). A detailed experimental procedure is provided for the methyl ester (compound 1),ethyl ester (compound 2), and butyl ester (compound 3) of the sophorolipids (p. 782, column 1, paragraphs 4 and 5; p. 782, column 2, first paragraph). The methyl, ethyl and butyl esters of sophorolipids were then subjected to lipase-catalyzed esterification with vinyl acetate or vinyl acrylate (p. 785, Scheme 2; p. 785-786, bridging paragraph) to yield regioselectively acylated sophorolipids. A detailed experimental procedure is provided for the synthesis of the 6',6"-diacetate derivative of the butyl ester of sophorolipid (compound 9, p. 783, column 1, second full paragraph). Bisht *et al.* further disclose that sphorolipids have importance in the treatment of autoimmune disorders, regulation of angiogenesis, *in vivo* and *in vitro* antiendotoxic shock activity, and *in vivo* cancer treatment/antitumor cell activity by cytokine upregulation (p. 781, column 1, first incomplete paragraph).

In the purification of compound 9, the sophorolipid analogue was eluted using a chloroform/methanol solvent mixture. It is the Office's position that chloroform/methanol can function as an excipient. Thus, the purified product in a chloroform/methanol solution is considered to suffice as a dispensable solution of sophorolipids.

Applicants are requested to note that the recitation "having spermicidal and/or antiviral properties" is considered an inherent property of the sophorolipids. When, as here, the prior art appears to contain the same compositions and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

The method for the preparation of sophorolipid analogues, disclosed by Bisht *et al.*, anticipates claims 58-63.

Response to Arguments

Applicant's arguments filed 25 August 2008 with respect to the rejection of claims 1, 3, 5-8 and 55-57 made under 35 USC § 102(b) as being unpatentable over Bisht *et al.*, have been fully considered but they are not persuasive.

Applicants argue that Bisht *et al.* do not disclose a method for producing sophorolipid esters that are formulated to be dispensed or applied to kill or inhibit sperm or viruses. Moreover, Applicants argue that Bisht *et al.* do not specifically teach how the sophorolipids may be used to treat disorders.

Applicant's arguments are not persuasive because the rejection in the Office Action dated 27 February 2008 is for the claims filed on 28 November 2007, which were directed towards a method for preparing dispensable sophorolipids and not dispensable sophorolipid esters. With regards to the argument that Bisht *et al.* do not specifically teach that the sophorolipids are formulated to be dispensed, it is the Office's position that an aqueous solution of sophorlipids is capable of being dispensed, and thus meets the limitations of the claims as filed on 28 November 2007, as indicated in the Office Action dated 27 February 2008.

With regards to the argument that Bisht *et al.* do not specifically teach how the sophorolipids may be used to treat disorders, this limitation was also not claimed. The claims are drawn towards a method of preparing dispensable sophorolipids, and the recitation "having spermicidal and/or antiviral properties" is considered an inherent property of the compound. When the prior art appears to contain the same compositions and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562

F.2d 1252, 195 USPQ 430 (CCPA 1977). It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

The rejection is still deemed proper and is therefore adhered to.

Applicant's arguments filed 25 August 2008 with respect to the rejection of claims 1-3, 5-8, 12, 28-30 and 55-57 made under 35 USC § 103(a) as being unpatentable over Bisht *et al.*, in view of U.S. Patent No. 5,545,401 to Shanbrom, have been fully considered but are moot in view of Applicant's amendments filed 25 August 2008. Furthermore, Applicant's arguments regarding Bisht *et al.* are as addressed above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 10, 11, 13 and 14 of copending Application No. 11/020,683.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method of making sophorolipids via fermentation of *C. bombicola* based on the same sophorolipid esters claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant has indicated, in the response filed on 25 August 2008, that upon allowance of the instant patent application, appropriate terminal disclaimers or other remarks will be filed at that time to address any double patenting rejections.

The provisional rejection of claims 1-3, 5, 6, 28-30 and 55 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 11/020,683 is thus **maintained**.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-

270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
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